UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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In This Issue

NEW: OIA August Office Hours

The next OIA office hours will be held on September 12, 2023 from 10-11 am and can be accessed at that time here.

NEW: Stakeholders Needed for OIA SOP Review

OIA is in the process of a wholesale revamp of our SOPs. While many of our SOPs focus on how staff in OIA do their jobs (e.g. review submissions, conduct meetings, determine the level of review, etc.), some of our SOPs instruct investigators and their teams on how to conduct their research (e.g. conduct informed consent, what needs IRB review before being implemented, who can serve as a legally authorized representative, etc.).

In recognition of this, we want to make sure the SOPs we eventually publish are both understandable and reasonable. For that, we need your help. We need folks who do this every day to review our proposed SOPs and meet with us to provide feedback. If you're interested in getting a sneak peek and providing your thoughts on our new SOPs, sign up to be a part of our stakeholder team here.

Whether or not you are able be a part of our stakeholder team, watch out for newsletters in the coming months announcing our SOP changes.

NEW: HIPAA Authorization Forms, Translations, and Guidance

This article comes from the UCSD Office of Compliance and Privacy (OCP) in collaboration with Rady Children's.

UC San Diego Research HIPAA Authorization Forms, Translation Certifications, and Guidance

If you are conducting research at UC San Diego and require a Research HIPAA Authorization you can find it on the UC San Diego Health Sciences Office of Compliance and Privacy's (OCP) intranet website at this link:

Health Insurance Portability and Accountability Act (HIPAA) in Research

There you will find the UCOP-approved research HIPAA authorization form (v2014) in English as well as in a variety of other languages, including their Translation Certifications.

If you have questions about completing these forms correctly, please review our Guidance for Research HIPAA Authorization Forms on the same webpage.

For answers to frequently asked questions about the use of the research HIPAA authorization, please visit our intranet website at this link:

HIPAA FAQs

Please contact the OCP with any questions at 1-844-234-7487 or hscomply@health.ucsd.edu.

Rady Children's Hospital-San Diego Research HIPAA Authorization Forms and Translation Certifications

If your research study is affiliated with Rady Children's Hospital-San Diego (RCHSD) and you require an RCHSD Research HIPAA Authorization, it can be found on the OCP website at the link above. If you do not have access to the OCP intranet site, the forms can be accessed through the following RCHSD intranet website links:

HIPAA Authorization Form Guidance

HIPAA Permission to Use Protected Health Information for Research - RCHSD Only [English] [Spanish] [Translation Certificate]

HIPAA Permission to Use Protected Health Information for Research - RCHSD & UCSD [English] [Spanish] [Translation Certificate]

Please contact RCHSD Research Administration at Research@rchsd.org with any questions.

NEW: Submitting a Funding Proposal? Don't Wait to Submit to OIA

UCSD researchers collectively bring in an extraordinary amount of funding from outside sources to help support their research, but these funders need to see certain things before they hand over any money. This includes IRB approvals or determinations when there are human subjects involved.

In OIA, we strive to be partners with our researchers and not stand in the way of getting research started. OIA often receives requests for rush approvals and reviews when Just In Time (JIT) notices come out. While we are happy to accommodate, these tend to bog down our review process for other researchers. In addition, there may be unforeseen complications with how research is proposed which means it cannot be easily approved even if it is moved to the front of the line.

As such, we ask that after researchers submit their proposals for funding, if the research will involve human subjects, go ahead and submit an application for review

to OIA. That way, if something unforeseen arises there is time to deal with it without putting research funding in jeopardy.

Please keep in mind that the normal OIA review process can take from 6-8 weeks from the time of submission, so be sure to get those studies submitted with plenty of time for review. Our office (and your fellow researchers) thank you!

Need help with a submission? Contact us at irb@ucsd.edu and one of our analysts will be happy to assist.

NEW: Reliances - See Something? Say Something

When OIA agrees to rely on an outside IRB for review of human subjects research, we still perform an administrative review to ensure UCSD's local context requirements are being met. If using Advarra or WCG, this happens just before their IRB approves UCSD as a study site. If using another IRB, this happens before OIA provides clearance to submit to the reviewing IRB.

During the reliance process, the reviewing IRB might ask researchers to sign off on various language in consent forms or changes to other documents. If you see something at these times that clearly doesn't match UCSD's local context requirements, don't be afraid to say something to the reviewing IRB. It could be an honest mistake (the people working at other IRB are human too) or it could be an issue with how they've interpreted our instructions or comments.

While OIA will point out any we catch and can help work with the reviewing IRB to sort out any issues, this can delay studies being approved in a timely manner. So remember, if you see something that looks wrong, say something.

Working on a reliance with an external IRB and have questions? Contact our reliance team at irbrely@ucsd.edu.

NEW: Service Now Automatic Ticket Closure

Since OIA transitioned to the Service Now (SNOW) ticketing system to help handle incoming inquiries, anytime we receive an email at irb@ucsd.edu or irbrely@ucsd.edu a ticket is generated in SNOW. Our support analysts review each ticket and determine whether they can answer the question themselves or whether the ticket needs to be sent along to someone else in the office.

Once an answer has been provided, the SNOW system will automatically notify the sender that a solution has been proposed. The sender will receive an email notification with two options: "Accept Solution" or "I Still Need Help." Clicking "Accept Solution" will close the ticket and the sender will have the option to complete a brief survey about their experience. Clicking "I Still Need Help" will reopen the ticket and allow the sender to provide more information, ask another question, or follow-up.

If no action is taken once a solution is proposed, the system automatically closes the ticket after 3 business days with no response. If a ticket is accidentally closed or wasn't responded to within the 3 business days (we all get busy, it happens) and additional assistance is needed, the sender will be able to open a new ticket or they can duplicate the previous ticket.

Please do not continue to respond to a ticket that has been closed as our office won't receive the message and any assistance will be delayed.

Reminder: Updated IRB Fees for UCSD Investigators

OIA currently charges three fees to UCSD investigators as described on our IRB Review Fees page. In light of the fact that these fees have not been evaluated in over three years and the significant changes that have occured in OIA during that time period, OIA was asked to re-evaluate our fees.

As a result of that re-evaluation, the following fee changes will apply to submissions made starting July 1, 2023:

- The fee for initial review of industry funded studies **will not** increase and will remain at $2700 + 30% F&A for a total of $3510
- The fee for annual/continuing review of industry funded studies **will** increase by $200 to $1200 + 30% F&A for a total of $1560
- The one-time fee for using a commercial external IRB (e.g. WCG/WIRB and Advarra) has been clarified to only pertain to studies which are funded in part or in whole by industry sponsors and **will** increase by $200 to $1200 + 30% F&A for a total of $1560

What if my study is unfunded?

Unfunded studies of UCSD investigators will continue to be reviewed by the UCSD IRB without charge. None of the above fees apply to unfunded studies.

What if my study only has federal/non-industry funding?

Studies with only federal and/or non-industry funding will remain exempt from the IRB fees listed above.

Will already approved industry-funded studies be grandfathered in to the old fee schedule?

No, previously approved studies will not be grandfathered in to the old fee schedule. All submissions eligible for billing submitted to OIA on or after July 1, 2023 will be billed at the new rate.

Why are the fees increasing?

There are a variety of reasons for the two fee increases above. First, due to inflation, periodic mandatory salary and benefits increases, and necessary increases in OIA staffing, the cost of performing these reviews has increased. Second, as pointed out on the OCGA website, UC policy requires that industry sponsors must cover the costs of the project. As the stewards of the taxpayer money that is used to fund our instituion, we cannot subsidize research for industry sponsors and so the rates have to periodically increase.

Reminder: New IRB Fee for UCSD Investigators

Starting July 1, 2023 a **new** one-time fee will be implemented for funded studies ***regardless of funding source*** where the UCSD IRB serves as the IRB of Record for external sites. This fee will cover UCSD IRB's review of the outside investigator at the external site and the local context information (e.g. site specific policies, regulations, laws, etc.) as well as any local documents. The new fee will be $615 + 30% F&A for a total of $800 **per site** for which the UCSD IRB will provide review.

What if my study is unfunded?

Unfunded studies of UCSD investigators will continue to be reviewed by the UCSD IRB without charge. The new fee will not apply to unfunded studies.

What if my study is funded by someone other than an industry sponsor?

For studies with any kind of funding ***including federal funding*** where the UCSD IRB will be the IRB of Record for external sites, these studies will be subject to the new one-time fee of $800 per site. This fee should be incorporated into the budgets for studies with a proposal due on or after July 1, 2023. For studies where a proposal is not required, new awards or contracts executed on or after July 1, 2023 should have this fee included in their budgets.

What counts as an external site?

RCHSD and SIO do not count as external sites for the purposes of the new one-time fee being implemented. Any other site/institution would be considered an external

site. This includes community clinics, other academic institutions, and other organizations for which the UCSD IRB is asked to provide IRB review and oversight.

Why is this new fee being created?

In the wake of the NIH's single IRB mandate and the Revised Common Rule's single IRB requirment, the work associated with multi-center studies for OIA has increased. When the UCSD IRBs serve as the single IRB for multi-center studies, OIA staff have to negotiate and execute reliance agreements, review and interpret local laws and policies at the external sites, and evaluate investigators we aren't familiar with. All of this comes at an additional cost which is not otherwise covered by OIA's current funding streams.

Reminder: Kuali KBAs

Knowledge Base Articles (KBAs) are an important part of the transition from the legacy eIRB system to Kuali. These articles help provide additional instruction and guidance about how to use the Kuali system. The research knowledge base containing KBAs for all of UCSD research can be found here.

Administrative Determinations

The OIA generally has 5 types of administrative determinations it can make:

- A study is not human subjects research
- UCSD/RCHSD is not engaged in the human subjects research
- The research qualifies for an exempt determination
- The research will rely on a non-UCSD IRB for review
- The research involves indefinite plans or delayed onset

The KBA on this topic walks users through how to submit each of the 5 types of determination applications above.

Amendments

The KBA on this topic walks users through the process of submitting an amendment and some particular nuances of how to use the Kuali IRB system.

Renewals

The KBA on this topic walks users through the process of submitting a renewal application.

Reportable Events

The KBA on this topic walks users through the process of submitting a reportable event application.

Closures

The KBA on this topic walks users through the process of submitting a closure application.

Reminder: Renewal of Business Systems Accounts

Since access to Kuali is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kuali. Those accounts are generally good for only a year and need to be renewed. As such, we want to remind everyone about this.

If you are a **user** who has a business systems account that you use to access Kuali, check in with the department who sponsored your account to see if there is anything they need you to do to ensure your account is renewed.

If you have **sponsored** someone for a business systems account, please be sure to follow your departmental policies on renewing (or not) accounts in a timely fashion so that researchers do not lose access to Kuali. Furthermore, please be on the lookout for automated emails asking you te renew access for these individuals throughout the course of the year.

Reminder: Getting Help

Kuali IRB Knowledge Base Articles (KBAs) are part of the growing Research Knowledge Base. We generate new articles and update older articles in response to trends in questions or problems submitted by the research community.

Install and enable the WalkMe extension in your browser to get contextual help as you navigate Kuali IRB. This includes tips about using the system as well as key regulatory background. The extension is approved for Campus and Health Sciences computers.

Contact OIA by email at irb@ucsd.edu with questions or to report errors/issues. For questions about Kuali in relation to single IRB/reliance arrangements, contact irbrely@ucsd.edu.

Please be sure to include the protocol number, if available. This will help the OIA team triage and troubleshoot.

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